prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 30, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–14277 Filed 6–6–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation; Grant to Metropolitan Family Services

AGENCY: Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), Department of Health and Human Services (DHHS)

ACTION: Award announcement.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to Metropolitan Family Services to strengthen the relationship between fathers and their children, increase their access to the labor force, improve their financial literacy, and strengthen their support systems.

As a Congressional set-aside, this 17-month project is being funded noncompetitively. Metropolitan Family Services is uniquely qualified to implement this project because of its decades long experience in providing services for strengthening families and communities. The cost of this 17-month project is $400,000.

FOR FURTHER INFORMATION CONTACT: K.A. Jagannathan, Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, telephone: 202–205–4829.

Dated: May 28, 2002.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 02–14320 Filed 6–6–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0587]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 8, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension (OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601). Section 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under 21 CFR 610.60, 610.61, and 610.62. Section 601.12(a) provides the general requirements for submitting a change to an approved application. Section 601.12(b), (c), and (d) requires applicants to follow specific procedures in informing FDA of each change, established in an approved license application, in the product, production process, quality controls, equipment, facilities, or responsible personnel. The appropriate procedure depends on the potential for the change to have a substantial, moderate, minimal, or no adverse effect on the safety or effectiveness of the product. Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures in reporting labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes. Section 601.45 requires applicants to submit to the agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements. Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a). Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a). Section 601.28 requires sponsors of licensed biological products to submit the information in section